

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Yoshihisa NISHIBE, et al.

Appln. No.: 09/446,276

Filed: December 21, 1999

For: PHARMACEUTICAL COMPOSITION FOR APPLICATION TO MUCOSA



Group Art Unit: 1615

Examiner: Not yet assigned

REQUEST FOR REFUND

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Applicants hereby respectfully request a refund in the amount of \$396.00 which was incorrectly charged to Deposit Account No. 19-4880 on May 1, 2000 for Excess Claims over 20. This refund is to be credited to Deposit Account No. 19-4880.

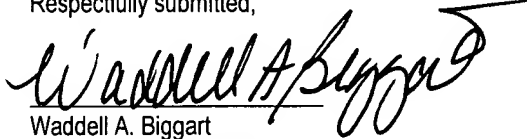
Applicants submit that the Government Filing Fee, after consideration of Article 19 Amendments is as follows:
Claims 1 & 3 are independent (Claim 2 was cancelled by the Article 19 Amendment);
Claims 4-7 are multiply dependent (dependent on claims 1 & 3); and
Claims 8-30 are improper multiply dependant claims each of which would count as 1 claim.

The total claim count is 33 claims with 2 independent claims for a total filing fee of \$1,3334.00 which was submitted along with the application papers on December 21, 1999.

Copies of the Deposit Account Monthly Statement showing the charge to our account, the transmittal letter, the Article 19 Amendment and a copy of check no. 144107 in the amount of \$1,334.00 are attached.

A duplicate copy of this paper is attached.

Respectfully submitted,


Waddell A. Biggart
Registration No. 24,861

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MACPEAK & SEAS, PLLC
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Telephone: (202) 293-7060
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Date: December 1, 2000

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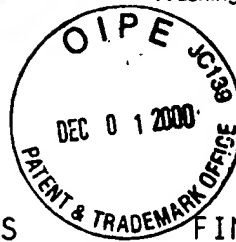


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MO.	DAY	YR.						
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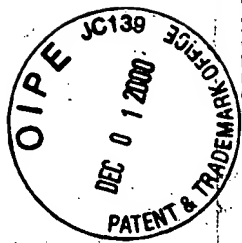
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SUGHRUE, MION, ZINN, MACPEAK & SEAS, PLLC 2100 PENNSYLVANIA AVENUE, N.W., WASHINGTON, D.C. 20037-3202

INVOICE DATE	INVOICE NO.		GROSS	NET INVOICE
12/20/99	OPER: CLF 124001 Q57234	PCT Application		840.00
12/20/99	OPER: CLF 124001 Q57234			234.00
12/20/99	OPER: CLF 124001 Q57234			260.00
CHECK NO.	CHECK DATE	COMMISSIONER OF PATENTS	TOTAL GROSS	NET CHECK
144107	12/20/99 10456			1,334.00

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Wade A. Peggant

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Assistant Commissioner for Patents
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December 21, 1999



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TELEPHONE (03) 3503-3760
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ATTN: BOX PCT

Re: Application of Yoshihisa NISHIBE, Wataru KINOSHITA and Hiroyuki KAWABE
PHARMACEUTICAL COMPOSITION FOR APPLICATION TO MUCOSA
Our Reference: Q57234
PCT/JP99/02126, filed April 21, 1999

Dear Sir:

Applicants herewith submit the attached papers for the purpose of entering the National stage under 35 U.S.C. § 371 and in accordance with Chapter I of the Patent Cooperation Treaty. Attached hereto is the application identified above which is a translation of PCT International Application No. PCT/JP99/02126, filed April 21, 1999, comprising the specification, claims, four (4) sheets of drawings, executed Declaration and Power of Attorney, English translation of Article 19 Amendments, Information Disclosure Statement, PTO Form 1449 with references, International Search Report, executed Assignment and PTO Form 1595.

The Government filing fee, after consideration of Article 19 Amendments, is calculated as follows:

Total Claims	33 - 20 =	13 x \$18 =	\$ 234.00
Independent Claims	2 - 3 =	0 x \$78 =	\$ 000.00
Base Filing Fee	(\$840.00)		\$ 840.00
Multiple Dep. Claim Fee	(\$260.00)		\$ 260.00
TOTAL FILING FEE			\$ 1,334.00
Recordation of Assignment Fee			\$ 40.00
TOTAL U.S. GOVERNMENT FEE			\$ 1,374.00

Checks for the statutory filing fee of \$ 1,334.00 and Assignment recordation fee of \$ 40.00 are attached. You are also directed and authorized to charge or credit any difference or overpayment to Deposit Account No. 19-4880. The Commissioner is hereby authorized to charge any fees under 37 C.F.R. 1.492; 1.16 and 1.17 which may be required during the entire pendency of the application to Deposit Account No. 19-4880. A duplicate copy of this transmittal letter is attached.

Priority is claimed from:

Japanese Patent Application
10-110887 (Pat. Appln.)
10-110888 (Pat. Appln.)

Filing Date
April 21, 1998
April 21, 1998

The Office is invited to contact the above firm on any question which might arise on the above-named application. Any contact that the Office might need to make should be directed to the undersigned at (202)293-7060.

Respectfully submitted,
SUGHRUE, MION, ZINN, MACPEAK & SEAS
Attorneys for Applicant(s)

By

Waddell A. Biggart
Waddell A. Biggart

Registration No. 24,861

WAB:clf

TO THE INTERNATIONAL BUREAU OF THE WORLD
INTERNATIONAL PROPERTY ORGANIZATION
34, Chemin des Colombettes
1211 Geneva 20, Switzerland



"Amendment of the claims under Article 19(1)(Rule 46)"

International Application No. PCT/JP99/02126

(Our Ref.: G836-PCT)

Agent:

(Name) Ishida Takashi

(氏名) 石田 孝士 (7751) 敬



(Address) A. AOKI, ISHIDA & ASSOCIATES

Toranomon 37 Mori Bldg., 5-1, Toranomon

3-chome, Minato-ku, Tokyo 105-8423 Japan

The applicant requests amendment of the claims of the present international application, based on Article 19, of the PCT, and transmits herewith newly amended claims. We believe the amendment does not go beyond the disclosure in the original international application.

An outline of the amendment is as follows.

1. Original claim 2 is cancelled.
2. Original claims 17, 23 and 25 to 29 are amended.
3. Other claims are maintained without change.

The applicant also files the attached brief statement which explains the amendment, and indicates any impact that the amendments therein might have on the description.

Explanation according to Article 12(1) of PCT

The claims described in the replaced papers relate to the original claims as follows.

- (1) Claim 2 is cancelled.
- (2) In claim 17, "claims 1 to 16" is amended to --claims 1 or 3 to 16--.
- (3) In claim 23, "claims 1 to 22" is amended to --claims 1 or 3 to 22--.
- (4) In claim 25, "claims 1 to 24" is amended to --claims 1 or 3 to 24--.
- (5) In claim 26, "claims 1 to 24" is amended to --claims 1 or 3 to 24--.
- (6) In claim 27, "claims 1 to 26" is amended to --claims 1 or 3 to 26--.
- (7) In claim 28, "claims 2 to 27" is amended to --claims 3 to 27--.
- (8) In claim 29, "claims 2 to 28" is amended to --claims 3 to 28--.

to the mucosa according to claim 8, wherein said osmotic pressure-controlling agent is a water-soluble sugar.

12. The pharmaceutical composition for application to the mucosa according to claim 11, wherein said osmotic pressure-controlling agent is glucose.

13. The pharmaceutical composition for application to the mucosa according to claim 1 or any of claims 3 to 12, wherein said water-insoluble and/or water-low soluble substance is a cellulose.

14. The pharmaceutical composition for application to the mucosa according to claim 13, wherein said cellulose is crystalline cellulose.

15. The pharmaceutical composition for application to the mucosa according to claim 1 or any of claims 3 to 12, wherein said one or more water-insoluble and/or water-low soluble substance is present as solid particles in an aqueous medium.

16. The pharmaceutical composition for application to the mucosa according to claim 1 or any of claims 3 to 12, wherein said one or more water-insoluble and/or water-low soluble substance is dispersed as solid particles in an aqueous medium.

17. (Amended) The pharmaceutical composition for application to the mucosa according to any of claims 1 or 3 to 16, further comprising a water-soluble polymer substance.

18. The pharmaceutical composition for application to the mucosa according to claim 17, wherein said water-soluble polymer is one or more selected from the group consisting of alginic acid, polyethylene glycol, glycerin, polyoxyethylene polyoxypropylene glycol, propylene glycol, pectin, low methoxyl pectin, guar gum, gum arabic, carrageenan, methyl cellulose, carboxymethyl cellulose sodium, xanthan gum, hydroxypropyl cellulose, and hydroxypropyl methyl cellulose.

19. The pharmaceutical composition for application to the mucosa according to claim 18, wherein said water-

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soluble polymer is carboxymethyl cellulose sodium.

20. The pharmaceutical composition for application to the mucosa according to claim 18, wherein said water-soluble polymer is xanthan gum.

5 21. The pharmaceutical composition for application to the mucosa according to claim 18, wherein said water-soluble polymer is hydroxypropyl methyl cellulose.

22. The pharmaceutical composition for application to the mucosa according to claim 17, wherein the combination of said water-insoluble substance and water-soluble polymer is crystalline cellulose carmellose sodium.

23. (Amended) The pharmaceutical composition for application to the mucosa according to any of claims 1 or 3 to 22, further comprising a surfactant.

15 24. The pharmaceutical composition for application to the mucosa according to claim 23, wherein said surfactant is polysorbate 80.

25. (Amended) The pharmaceutical composition for application to the mucosa according to any of claims 1 or 3 to 24, wherein said medicament is a water-soluble medicament.

26. (Amended) The pharmaceutical composition for application to the mucosa according to any of claims 1 or 3 to 24, wherein said medicament is a liposoluble medicament.

27. (Amended) The pharmaceutical composition for application to the mucosa according to any of claims 1 or 3 to 26, wherein said mucosa is nasal mucosa.

28. (Amended) The pharmaceutical composition for application to the mucosa according to any of claims 3 to 27, wherein said hemostatic agent is one or more selected from the group consisting of tranexamic acid, epsilon aminocaproic acid, carbazochrome, carbazochrome sulfonate, carbazochrome sodium sulfonate, phytonadione, etamsylate, monoethanol amine oleate, thrombin, hemocoagulase, and adrenochrome monoaminoguanidine mesilate.

29. (Amended) The pharmaceutical composition for application to the mucosa according to any of claims 3 to 28, wherein the agent other than said hemostatic agent is one or more

selected from the group consisting of an antiallergic agent, an antihistamic agent, an anticholinergic agent, a steroid, a vaccine, and a substance for gene therapy, and the mucosa is nasal mucosa.

- 5 30. The pharmaceutical composition for application to nasal mucosa according to claim 29, wherein the agent other than said hemostatic agent is a steroid.